



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert Ashley Examiner: Unassigned
Serial No.: 10/757,656 Group Art Unit: Unassigned
Confirmation No: Unassigned Docket: 512-53 DIV
Filed: January 14, 2004 Dated: March 4, 2004
For: METHODS OF TREATING
ACNE

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I hereby certify this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on March 4, 2004

Signed: Carla Bryan

INFORMATION DISCLOSURE STATEMENT

Sir:

In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R. §1.56, Applicant submits herewith the following Information Disclosure Statement in accordance with the provisions of 37 C.F.R. §1.97 and §1.98.

U.S. PATENTS

<u>PATENTEE</u>	<u>PATENT NO.</u>	<u>ISSUE DATE</u>
Ramamurthy et al.	5,998,390	December 7, 1999
Gans	5,908,838	June 1, 1999
Ramamurthy et al.	5,827,840	October 27, 1998
Ritter	5,122,519	June 16, 1992

NON-PATENT PUBLICATIONS

1. Akamatsu, et al. "Effect of Keigai-Rengyo-To, a Japanese Kampo Medicine, on Neutrophil Functions: a Possible Mechanism of Action of Keigai-Rengyo-To in Acne," *The Journal of International Medical Research*, 25: 255-265 (1997).
2. Baer, et al. "High-Dose Tetracycline Therapy in Severe Acne," *Arch Dermatol*, 112:479-481 (April 1976).
3. Cheryl Guttman, "Emerging resistance changes face of antibiotic therapy for acne," *Dermatology Times*, January 2001, page 22.
4. Hirohiko Akamatsu, Maki Asada, Jinro Komura, Yasuo Asada, and Yukie Niwa, "Effect of Doxycycline on the Generation of Reactive Oxygen Species: A Possible Mechanism of Action of Acne Therapy with Doxycycline," *Acta Derm Venereol (Stockh)* 72:178-178 (1992).
5. Bodokh, Y. Jacomet, J. Ph. Lacour and J.P. Ortonne, "Minocycline Induces an Increase in the Number of Excreting Pilosebaceous Follicles in Acne Vulgaris," *Acta Derm Venereol (Stockh)*, 77:255-259 (1997).
6. W. J. Cunliffe, M.D., F.R.C.P., "Evolution of a Strategy for the Treatment of Acne," *J Am Acad Dermatol*, 16:591-9 (1987).
7. E. Anne Eady, Eileen Ingham, Christina E. Walters, Jonathan H. Cove, and William J. Cunliffe, "Modulation of Comedonal Levels of Interleukin-1 in Acne Patients Treated with Tetracyclines," *J. Invest Dermatol*, 101:86-91 (1993).
8. Boni E. Elewski, M.D., Beth A.J. Lamb, W. Mitchell Sams, Jr., M.D., and W. Ray Gammon, M.D., "In Vivo Suppression of Neutrophil Chemotaxis by Systemically and Topically Administered Tetracycline," *J Am Acad Dermatol*, 8:807-812 (1983).
9. Nancy B. Esterly, M.D., Nancy L. Furey, M.D., and Lillian E. Flanagan, B.S., "The Effect of Antimicrobial Agents on Leukocyte Chemotaxis," *The Journal of Investigative Dermatology*, 70(1):51-55 (1978).
10. Sainte-Marie, I. Tenaud, O. Jumbou and B. Dréno, "Minocycline Modulation of Alpha-MSH Production by Keratinocytes *In vitro*," *Acta Derm Venereol* 79:265-267 (1999).
11. Hoshiki Miyachi, M.D., Akira Yoshioka, M.D., Sadao Imamura, M.D., and Yukie Niwa, M.D., "Effect of Antibiotics on the Generation of Reactive Oxygen Species," *J Invest Dermatol*, 86(4):449-453 (1986).

12. Gerd Plewig, M.D., and Erwin Schöpf, M.D., "Anti-Inflammatory Effects of Antimicrobial Agents: An In Vivo Study," *The Journal of Investigative Dermatology*, 65:532-536 (1975).
13. M. Toyoda and M. Morohashi, "An Overview of Topical Antibiotics for Acne Treatment," *Dermatology*, 196:130-134 (1998).
14. Sheila E. Unkles, and Curtis G. Gemmell, "Effect of Clindamycin, Erythromycin, Lincomycin, and Tetracycline on Growth and Extracellular Lipase Production by *Propionibacteria* In Vitro," *Antimicrobial Agents and Chemotherapy*, 21:39-43 (1982).
15. G.F. Webster, K.J. McGinley, and J.J. Leyden, "Inhibition of Lipase Production in *Propionibacterium acnes* by Sub-Minimal-Inhibitory Concentrations of Tetracycline and Erythromycin," *British Journal of Dermatology*, 104:453-457 (1981).
16. Guy F. Webster, M.D., Ph.D., Susan M. Toso, M.S., and Lutz Hegemann, M.D., Ph.D., "Inhibition of a Model of In Vitro Granuloma Formation by Tetracyclines and Ciprofloxacin," *Arch Dermatol.*, 130:748-752 (1994).
17. Reynold C. Wong, M.D., Sewon Kang, M.P.H., Jan L. Heezen, L.P.N., John J. Voorhees, M.D., and Charles N. Ellis, M.D., "Oral Ibuprofen and Tetracycline for the Treatment of Acne Vulgaris," *J Am Acad Dermatol*, 11:1076-1081 (1984)
18. Kenneth S. Kornman and Edward H. Karl, "The Effect of Long-Term Low-Dose Tetracycline Therapy on the Subgingival Microflora in Refractory Adult Periodontitis," *J. Periodontol.*, 53(10):604-610 (October 1982).

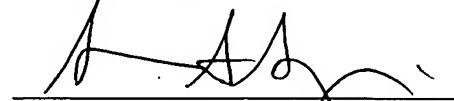
The above-identified references are listed on the enclosed Form PTO-1449. Copies of the references have been provided in the parent case U.S. Serial No.: 10/117,709.

The Examiner is respectfully requested to consider these references in their entireties, and to indicate that he or she has done so by initialing the enclosed Form PTO-1449.

In view of the present submission, it is believed that the present application is in all respects complete, and in condition for examination and favorable consideration.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicant's attorney at the telephone number set forth below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Susan A. Sipos', written over a horizontal line.

Susan A. Sipos, Esq.
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Attorney for Applicant

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 2-32) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	ATTY. DOCKET NO. 512-53 DIV	SERIAL NO. 10/757,656
	APPLICANT Ashley, Robert	CONFIRMATION NO. Unassigned
	FILING DATE January 14, 2004	GROUP Unassigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	5,998,390	12/7/99	Ramamurthy et al.			
	5,908,838	6/1/99	Gans			
	5,827,840	10/27/98	Ramamurthy et al.			
	5,122,519	6/16/92	Ritter			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Akamatsu, et al. "Effect of Keigai-Rengyo-To, a Japanese Kampo Medicine, on Neutrophil Functions: a Possible Mechanism of Action of Keigai-Rengyo-To in Acne," <i>The Journal of International Medical Research</i> , 25: 255-265 (1997).
		Baer, et al. "High-Dose Tetracycline Therapy in Severe Acne," <i>Arch Dermatol</i> , 112:479-481 (April 1976).
		Cheryl Guttman, "Emerging resistance changes face of antibiotic therapy for acne," <i>Dermatology Times</i> , January 2001, page 22.
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			E. Anne Eady, Eileen Ingham, Christina E. Walters, Jonathan H. Cove, and William J. Cunliffe, "Modulation of Comedonal Levels of Interleukin-1 in Acne Patients Treated with Tetracyclines," <i>J. Invest Dermatol</i> , 101:86-91 (1993).
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			Sainte-Marie, I. Tenaud, O. Jumbou and B. Dréno, "Minocycline Modulation of Alpha-MSH Production by Keratinocytes <i>In vitro</i> ," <i>Acta Derm Venereol</i> 79:265-267 (1999).
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			Gerd Plewig, M.D., and Erwin Schöpf, M.D., "Anti-Inflammatory Effects of Antimicrobial Agents: An In Vivo Study," <i>The Journal of Investigative Dermatology</i> , 65:532-536 (1975).
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		G.F. Webster, K.J. McGinley, and J.J. Leyden, "Inhibition of Lipase Production in <i>Propionibacterium acnes</i> by Sub-Minimal-Inhibitory Concentrations of Tetracycline and Erythromycin," <i>British Journal of Dermatology</i> , 104:453-457 (1981).
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